Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens)

Sponsored by the Ad Hoc International Relations Committee & the Ethics Committee



Current Concepts in Policy 6.0

- Definition of non-resident aliens
- Audit of non-resident alien transplants ("5% rule")
- Exportation and importation of deceased donor organs
- Ethical practices (with valuable consideration)
- Non-discrimination of non-resident alien transplant candidates
- Various others: community participation, fees, referrals, training



Core Problems of Current Policy 6.0 (1/2)

 Confusing mix of regulations, much of it irrelevant and outdated

- Much misunderstanding in transplant community about the audit policy
 - Programs find themselves in the "immigration business"
 - Programs may be unnecessarily hesitant to transplant non-resident aliens for fear of audit



Core Problems of Current Policy 6.0 (2/2)

- Minimal public "transparency" of practice with current data collection policy, which may undermine public trust
- Data collection does not permit adequate evaluation of which type of non-resident is being transplanted



Policy 6.2.5 (Community Participation)

- Policy suggests that Members "establish a mechanism for community participation and review of its candidate acceptance criteria"
 - This measure of transparency and public accountability is not being honored
 - Current realities of travel for transplantation and transplant tourism require appropriate oversight and transparency of the system in order to maintain public trust
 - Proposed changes attempt to increase public transparency regarding these circumstances



Goals of the Proposed Policy

- Create transparency in the deceased donor waitlisting and transplantation of non-citizen/nonresidents
- Understand the scope of "travel for transplantation" to the US
 - Phenomenon that may undermine the capacity to provide organs for its residents
- Provide accuracy in data collection and transparency in reporting of who is being transplanted



Proposed Modifications

- Delete policies that are not enforceable
- Change placement of organ export policy language
- Delete rule regarding 6 ad hoc organ imports
- Classify a person who considers the US a primary place of residence as a 'resident'
- Eliminate the greater than 5% audit trigger policy ("5% rule")
- Allow review of all listings and transplants of noncitizens/non-residents



Exportation of Deceased Donor Organs

Moves content of Policy 6.4 (Exportation and Importation of Organs-Developmental Status) to Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members)

Not changing the intent of the export language

Page 59 (export policy)



Importation of Foreign Deceased Donor Organs

- Retains ability to import organs ad hoc and through a formal agreement – requirements are in current policy;
- Delete requirement about establishing a formal agreement with a foreign agency if a Member imports more than 6 deceased donor organs in an ad hoc manner from that foreign agency
 - 6 is an arbitrary number; and
 - Small number of deceased donor organ imports that occur in a given year
 - 85 transplants with imported deceased donor organs during 2003 through 2009



Current Residency Definitions in Policy

- 6.1.1 (Non-Resident Alien)
 - A non-resident alien is an individual granted permission by the United States Government to enter the United States on a temporary basis as a non-immigrant alien for purposes which include tourism, business, education, medical care, or temporary employment.
- 6.1.2 (Domestic, American Candidate or Resident Alien)
 - A domestic, American candidate or resident alien is an individual who is either an American citizen or is an immigrant alien granted permanent resident status by the United States Government or any individual, regardless of immigrant status, qualified for health care entitlement funds from state or federal government sources.



Recent Board of Directors' Approval

- New citizenship/residency categories on data collection forms:
 - US citizen
 - Non-US Citizen/US Resident
 - Non-US Citizen/Non-US Resident,
 Traveled to the US for Reason Other than Transplant
 - Non-US Citizen/Non-US Resident, Traveled to US for Transplant

Current OPTN forms collect the year of entry to the US for Non-US Citizens/Non-US Residents.



Align Policy Definitions with Revised Data Collection

- 6.1.1 (Non-US Citizen/US Resident)
 - A person who is not a citizen of the United States, who is present in the United States, and for whom the United States is the primary place of residence.
- 6.1.2 (Non-US Citizen/Non-US Resident)
 - A person who is not a citizen of the United States and for whom the United States is not the primary place of residence.



Residency Status Self-Reported – Same as Today

- Candidate self declares citizenship or residency
- Self-reporting these data have limitations similar to other demographic information, which is similarly self-reported
- Status may be self-evident from demographic information



New Audit and Reporting Policy

6.3 (Audit and Reporting of Non-US Citizens/Non-US) Residents) – As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and, at its discretion, audit all member transplant center activities pertaining to transplantation of non-US residents/non-US citizens. At member transplant centers where non-US residents/non-US citizens are listed for transplant, the Ad Hoc International Relations Committee shall review the circumstance and justification for listing any non-US resident/non-US citizen traveling to the United States for transplant. Review does NOT automatically

OPTN -

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entail referral to the MPSC

New Transparency in Reporting Policy

 6.3.1 (Transparency in Reporting Listings and Transplants of Non-US Citizens/Non-US Residents) – The Committee shall prepare and provide public access to an annual report of member transplant center activities related to the transplantation of non-US citizens/non-US residents.

Data will be redacted to protect privacy



Additional Work for the Committees

Develop and make available criteria for the review proposed in the new Policy 6.3



What the Proposal Does Not Do

- Does not seek to prohibit non-US citizens/nonresidents from being wait-listed and transplanted
- Makes no attempt to use citizenship or residency status in the allocation of organs
- Does not seek to punish programs for transplanting non-residents, but does seek to provide transparency



Questions?

What should be considered as part of the review proposed in Policy 6.3?

